



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,552	04/02/2001	In Suk Han	1527.MBIO.NP	9416

7590

06/03/2003

Robert R Mallinckrodt
M- Biotech Inc
2411 South 1070 West #3
Salt Lake City, UT 84119

EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824552

Applicant(s)

Hsu et al

Examiner

A. K. F.

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/12/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-18, 21+22 is/are pending in the application.
- Of the above claim(s) 7-14 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-6, 15-18, 21+22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- *Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, File 1 4/20/02 + 7/24/07 Reper No(s) ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

In a response of 3/12/03 to a restriction requirement of 2/5/03, applicants elected Group I claims 1-6 and 15-18, and amended claims by canceling claims 19 and 20, and adding new claims 21 and 22 depending on claim 1.

5 Claims 7-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10 of 3/12/03.

Claims examined on the merits are 1-6, 15-18, 21 and 22.

10 **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

15 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 15-18, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 Claims 1 and 15 are confusing by expressing catalase concentration as units/ml of polymer matrix. The polymer matrix is a solid, and it is uncertain how one measures a ml of a solid polymer matrix.

In claims 2 and 16, expressing crosslinking proportion as mol% is uncertain as to meaning and scope since mol% represents an amount of substance present. However, crosslinking proportion is not a substance.

25 Claims 15-18 are unclear by the preamble of claim 15 requiring a method of making a polymer matrix containing an analytic enzyme that

generates hydrogen peroxide. However, claim 15 merely requires a step of co-immobilizing an analytic enzyme with catalase. This single step will not produce a polymer matrix as required in the preamble.

Additionally, bridging lines 1 and 2 of claim 15, and in claim 22, "analyte-responsive drug delivery device" is uncertain as to meaning and scope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said
15 subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes
20 that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the
25 examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 15-18, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han et al (WO 99/17095).

The claims are drawn to a polymer matrix containing catalase co-
30 immobilized with an analytic enzyme such as glucose oxidase, wherein the

concentration of catalase ranges from about 100 to about 1000 units/ml. Also claimed is the polymer matrix in combination with a biosensor, a method of making the matrix by co-immobilizing an analytic enzyme and catalase.

5 Han et al disclose a biosensor having a pH sensitive hydrogel containing co-immobilized glucose oxidase and catalase (page 6, lines 14-16, page 15, lines 8-10, page 16, lines 28-30, and claims 10 and 18). The catalase consumes hydrogen peroxide that deactivates the glucose oxidase.

10 It would have been obvious to provide in the catalase-containing hydrogel of Han et al an amount of catalase that consumes sufficient hydrogen peroxide to prevent inactivation of glucose oxidase. Selecting this amount of catalase would have required only limited routine experimentation and been obvious to the ordinary skilled artisan. The
15 conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references.

While Han et al is a PCT of parent application 09/308,392 of which the present application is a CIP, Han et al is a proper reference since Han et al was published prior to the filing date of the present
20 application and has a different inventive entity from the inventive entity of the present invention, and the present invention is not disclosed in the parent application.

Double Patenting

25 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

5 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this
10 application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15 Claims 1-6, 15-18, 21 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,268,161 B1. Although the conflicting claims are not identical, they are not patentably
20 distinct from each other because claims 10 and 18 of the patent require a pH sensitive hydrogel containing co-immobilized glucose oxidase and catalase, and determining an amount of catalase to prevent glucose oxidase inactivation would have been obvious for reasons set forth in the rejection above over Han et al.

Any inquiry concerning this communication or earlier communications
25 from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a
30 message can be left on voice mail.

Application Number: 09/824,552
Art Unit: 1651

Page 6

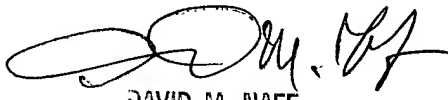
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or
5 (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10

DMN
6/2/03


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 12657